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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,646	07/19/2006	Robertus Mattheus Felix Van Der Weiden	2007-1006-1	7719

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EXAMINER	
DORNA, CARRIE R	
ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
02/16/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/586,646	VAN DER WEIDEN, ROBERTUS MATTHEUS FELIX	
	Examiner	Art Unit	
	Carrie Dorna	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-60,64,66,68-75,114-116 and 119-121* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-60,64,66,68-75,114-116 and 119-121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 February 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 December 2010 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 54-60, 64, 66, 68, 71, 72, 74, 114-116, and 119-121** are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.).

Regarding **claim 54**, Thierfelder et al. teaches an assembly for use in the attachment of a patient's vaginal apex or uterus or rectum to her/his spine, comprising: a first tube (trocar, [0139]) having a length adapted to the distance from an outer wall of the patient's abdomen to a sacrum (Device is capable of extending from the outer wall of the patient's abdomen to the sacrum as that distance depends on the dimensions of the patient's anatomy, [0072]), the first tube (trocar, [0139]) being provided with a distal

end and comprising an opposite proximal end and having a first passage from the distal to the proximal end thereof (trocar necessarily has a lumen; [0139]); a second rod (*Figure 11, surgical article,* 40) having a length that at least equals the length of the first tube ([0072]; trocar, [0139]), the second rod (40) being provided with a distal end and comprises an opposite proximal end ([0072]); and at least one attachment device (*Figure 11, bone screw,* 44) configured for penetrating into the spine provided with a distal end for attachment to the sacrum and a proximal end for attachment of an end of a connector (*Figure 11, suture,* 43) configured for connection to the patient's vaginal apex or uterus or rectum ([0072]-[0073]), wherein the distal end of the second rod (40) and the proximal end of the attachment device (44) are formed for functional mutual engagement ([0072]-[0073]; see *Figure 11*), wherein the second rod (40) can be movably accommodated in the first tube ([0072]-[0073]; trocar, [0139]), the second rod (40) extending into the first tube (trocar, [0139]), wherein the distal end of the first tube (trocar, [0139]) is configured to be brought into engagement with the sacrum and at least a part of the connector (43) is attached to the attachment device (44) and situated within the first tube ([0072]-[0073]; trocar, [0139]), the part of the connector (43) is situated between the first (trocar, [0139]) and the second rod (40) ([0072]-[0073]; trocar, [0139]; see *Figure 11*), a distal end portion of the second rod (40) is narrowed for together with the first tube (trocar, [0139]) forming an accommodation space for said part of the connector (43) (see *Figure 11*; [0072]-[0073]; *Figure 11* depicts the surgical article 40 having a shaft 41 that paragraph [0139] teaches may be inserted through a trocar during the implantation procedure. The shaft 41 of the article 40 is necessarily

narrower than the inner lumen of the trocar and is clearly narrower than the remainder of the article 40. The suture 43 construed as the claimed “connector” is shown in *Figure 11*, and therefore, necessarily is also contained within the trocar during the procedure. Therefore, Thierfelder et al. teaches an "accommodation space" for the "connector” between the narrowed shaft 41 and the inner wall of the trocar.).

Regarding **claims 55 and 120**, Thierfelder et al. teaches that the second rod (40) can be rotatably and snugly accommodated in the first tube ([0072]-[0073]; trocar, [0139]).

Regarding **claim 56**, Thierfelder et al. teaches that the attachment device (44) is a bone screw (0072]-[0073]).

Regarding **claim 57**, Thierfelder et al. teaches that the proximal end of the second rod (40) is provided with means for rotation of the second rod (40) (surgical article has a motorized driver for rotating the shaft to implant the bone screw, [0072]-[0073]).

Regarding **claim 58**, Thierfelder et al. teaches that the means for rotation comprises an arm that is transverse to the second rod (40) (motorized driver necessarily comprises an arm portion that is transverse to the shaft so that rotational energy is transferred to the shaft, [0072]-[0073]).

Regarding **claim 59**, Thierfelder et al. teaches that the distal end of the second rod (40) is formed for fittingly, holding the proximal end of the attachment device (44) ([0072]-[0073]; [0139]).

Regarding **claim 60**, Thierfelder et al. teaches that the second rod (40) has an internal cavity, which is at least formed at the distal end (second rod necessarily has an internal cavity for containing the suture, see *Figure 11,* [0072]-[0073).

Regarding **claim 64**, Thierfelder et al. teaches that the second rod (40) has an internal cavity, which is at least formed at the distal end, and wherein the distal end of the second rod (40) forms an accommodation space for the proximal end of the means for attachment (44) and is provided with a passage to the side (see *Figure 11*), wherein an end portion of the said part of the connector (43) extends through the passage (see *Figure 11*; [0072]-[0073]).

Regarding **claims 66 and 119**, Thierfelder et al. teaches that the said part of the connector (43) comprises a mat of material enabling bodily tissue ingrowth (The suture 43 is formed of braided polyester, therefore the suture 43 is considered to be a "mat of material enabling bodily tissue ingrowth", [0069]). The mat is capable of being wrapped or shirred up around the second rod (40) (*Figure 11*).

Regarding **claim 68**, Thierfelder et al. teaches that the attachment device (44) has a diameter that at least almost corresponds to the diameter of the first passage (trocar lumen, [0139]; see discussion in claim 54).

Regarding **claim 71**, Thierfelder et al. teaches that the first tube (trocar, [0139]) is provided with a handle near the proximal end (trocar necessarily has some portion near the proximal end where the surgeon may grip the trocar to manipulate it properly, [0139]).

Regarding **claim 72**, Thierfelder et al. teaches that the connector (43) comprises one or more threads that are attached to the attachment device (44) (The suture 43 is considered to be the "connector". A portion of the suture 43 adjacent and attached to the bone screw 44 may be considered to be a “thread", while the remainder of the suture 43 may be considered to be a "mat". The suture 43 is formed of braided polyester, therefore this remainder of the suture 43 may considered to be a "mat of material enabling bodily tissue ingrowth", [0069]; [0072]).

Regarding **claim 74**, Thierfelder et al. teaches that the device is sterilely accommodated in hermetically closed packaging ([0067]).

Regarding **claim 114**, Thierfelder et al. teaches that the connector (43) comprise one or more threads (The suture 43 is considered to be the "connector". A portion of the suture 43 adjacent and attached to the bone screw 44 may be considered to be a “thread", while the remainder of the suture 43 may be considered to be a "mat". The suture 43 is formed of braided polyester, therefore this remainder of the suture 43 may considered to be a "mat of material enabling bodily tissue ingrowth", [0069]; [0072]).

Regarding **claim 115**, Thierfelder et al. teaches that the mat of material is attached to threads (The suture 43 is considered to be the "connector". A portion of the suture 43 adjacent and attached to the bone screw 44 may be considered to be a “thread", while the remainder of the suture 43 may be considered to be a "mat". The suture 43 is formed of braided polyester, therefore this remainder of the suture 43 may considered to be a "mat of material enabling bodily tissue ingrowth", [0069]; [0072]).

Regarding **claims 116 and 121**, Thierfelder et al. teaches that the connector (43) is capable of being completely positioned within the first tube (trocar, [0139]; see discussion for claim 54).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claim 69** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.) in view of U.S. Patent Application Publication No. 2002/0143234 (LoVuolo).

Regarding **claim 69**, Thierfelder et al. teaches all of the limitations of claim 54. Thierfelder et al. does not teach that the assembly comprises means for gauging.

However, LoVuolo teaches a device for suspending a bodily structure comprising a first tube (*Figure 2, cannula,* 18) that is provided with means for gauging (*Figure 2, stripes,* 44) related to the sliding of a second tube (*Figure 2, deploying rod,* 28) in the first tube (18) corresponding to the attachment length of the distal end of an attachment device (*Figure 2, anchor toggle,* 32) (Depth calibration stripes indicate the insertion depth of the cannula, which allows the surgeon to accurately access when the cannula is in the appropriate location to then deploy the anchor using the deploying rod, [0047], 0048], [0057]. Therefore, the stripes are related to the insertion depth of the second tube and the length of the sutures attached to the anchor, which is directly related to the

tension of the organ suspension). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the means for gauging of LoVuolo on the second tube of Thierfelder et al., because depth indicia allow the surgeon to accurately access when the delivery mechanism is in the appropriate location to then deploy the attachment device (LoVuolo, [0057]).

6. **Claims 70, 73, and 75** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.) in view of U.S. Patent No. 5,458,606 (Wortrich).

Regarding **claims 70, 73, and 75**, Thierfelder et al. teaches all of the limitations of claims 54 and 74. Thierfelder et al. does not teach that the distal end of the first tube is serrated, nor does Thierfelder et al. teach the use of a laparoscope or viewing screen.

However, Wortrich teaches a system for implanting a surgical tack in the sacrum to suspend a prolapsed pelvic organ that comprises a first tube (*Figure 5, sleeve,* 32) having a serrated distal edge (*Figure 5, terminal edge,* 38) (col. 4, lines 23-38), a laparoscope, and a viewing screen that is functionally connected to the laparoscope (col. 3, lines 60-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the laparoscope and viewing screen of Wortrich in the assembly of Thierfelder et al., because the laparoscope and viewing screen allows the surgeon to observe the surgical cavity remotely reduce patient recovery time, pain, and trauma (Wortrich, col. 1, lines 16-21 and col. 3, lines 63-67). Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a serrated edge on the distal tip of the first tube of Thierfelder et al. as taught by Wortrich,

because the serrated edge provides better engagement with the surface in which the attachment mechanism is to be placed (Wortrich, col. 6, lines 32-37).

Double Patenting

7. Applicant is advised that should claim 116 be found allowable, claim 121 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Response to Arguments

8. Applicant's arguments, see pages 12-16, filed 1 December 2010, with respect to the rejection of claims 54, 59, 60, 64, 66, 68-70, 72, 73, and 116 under 35 U.S.C. 102(b) and 103(a) citing at least Li have been fully considered and are persuasive. The rejection of claims 54, 59, 60, 64, 66, 68-70, 72, 73, and 116 under 35 U.S.C. 102(b) and 103(a) citing at least Li have been withdrawn.

9. Applicant's arguments filed 1 December 2010 with respect to the rejection of claims 54-60, 64, 66, 68-75, and 114-116 under 35 U.S.C. 102(b) and 103(a) citing at least Thierfelder et al. have been fully considered but they are not persuasive. Applicant contends that Thierfelder et al. does not anticipate the requirements of claim 54 as Thierfelder et al. does not teach that the surgical article is inserted through a trocar, or that the relative configuration of the first tube and second rod provides an accommodation space for the connector. The Examiner does not find these arguments

to be persuasive. Thierfelder et al. teaches in paragraphs [0072]-[0074] and *Figure 11* that a "preferred surgical article 40" is used to implant a bone screw 44 and attached suture 43 to the sacral bone for suspending a prolapsed pelvic organ (emphasis added). Paragraphs [0134]-[0139] teach a laparoscopic surgical technique for suspending a vaginal apex from bone screws placed in the sacrum. Paragraph [0139] specifically states that "[a] laparoscopic compatible surgical device may be used to place the bone anchors (e.g. screws). For example, a manual screw driver or a powered screw driver that is sized and shaped to fin in the cannula of a trocar may be utilized for this purpose" (emphasis added). Accordingly, the shaft 41 of the article 40 would necessarily be narrower than the inner lumen of the trocar used, and is clearly narrower than the remainder of the article 40 as shown in *Figure 11*. The suture 43 construed as the claimed "connector" is shown in *Figure 11*, and necessarily would also be contained within the trocar during the procedure. As such, Thierfelder et al. teaches an "accommodation space" for the "connector" between the narrowed shaft 41 and the inner wall of the trocar. Therefore, the previous grounds of rejection citing at least Thierfelder et al. have been maintained.

Conclusion

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued

examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Dorna whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. D./
Examiner, Art Unit 3735